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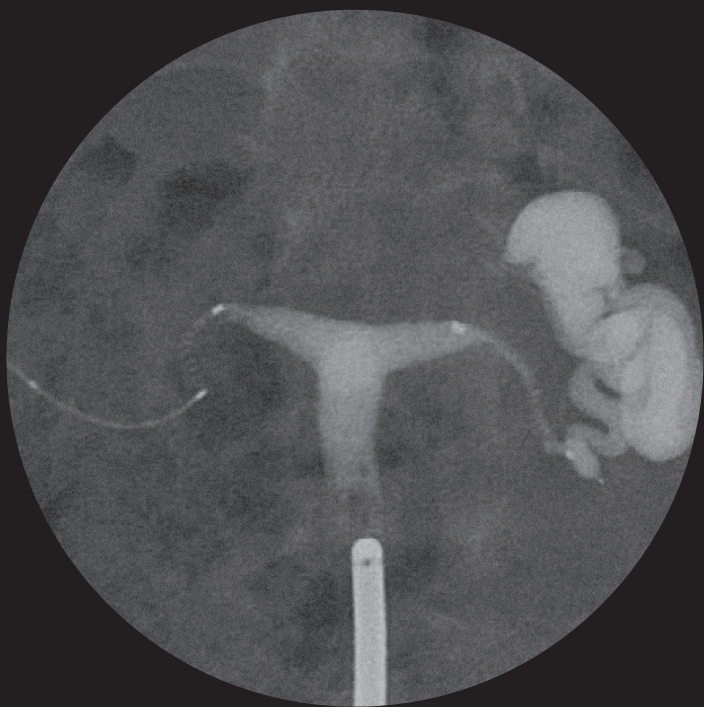
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8 Essure hysteroscopic tubal occlusion device for the treatment of hydrosalpinx prior to in vitro fertilization-embryo transfer in patients with a contraindication for laparoscopy.

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Abstract

Objective To investigate the success rate of proximal tubal occlusion with Essure devices in subfertile women with hydrosalpinges, and to observe the results of subsequent treatment with IVF.

Design Prospective, single arm, clinical study.

Setting University hospital and teaching hospital.

Patient(s) Ten women with uni- or bilateral hydrosalpinges prior to IVF. In all patients laparoscopy was contraindicated.

Intervention(s) Hysteroscopic placement of Essure devices in an office setting.

Main Outcome Measure(s) Placement rate, successful proximal tubal occlusion, and pregnancy rate after IVF. Result(s): All patients had successful placement of the Essure devices without any complications. Proximal tubal occlusion was confirmed by hysterosalpingography in 9 out of 10 patients. A 40% ongoing pregnancy rate was achieved with 20% live births after one IVF cycle and/or frozen embryo transfer.

Conclusion(s) Proximal occlusion of hydrosalpinges with Essure devices before IVF is a successful treatment for patients with a contraindication for salpingectomy.

Key Words Essure hysteroscopic tubal occlusion, Hydrosalpinges, IVF-ET

Introduction

The tubal factor accounts for up to 35% of female infertility, and is the most obvious indication for in vitro fertilization-embryo transfer (IVF-ET). Distal tubal occlusion may lead to formation of hydrosalpinges, which are found in 10% to 30% of all patients undergoing IVF-ET (1).

Patients with hydrosalpinges have been identified as a subgroup with significantly poorer outcomes of IVF-ET compared to tubal factor patients without hydrosalpinges. This has been demonstrated in two meta-analysis of retrospective studies concluding that hydrosalpinges were associated with a reduced chance of implantation and a increased risk of miscarriage (2,3). Especially patients with hydrosalpinges large enough to be visible on ultrasound are associated with the poorest IVF-ET prognosis (4,5).

The theories explaining the harmful effect of hydrosalpinges on IVF outcomes are multiple, and include the following: [1] a mechanical washout of the transferred embryos through tubouterine reflux of hydrosalpinx fluid, [2] a direct embryotoxic effect even when a low concentration of hydrosalpinx fluid is present in the uterine cavity, [3] a lower endometrial receptivity as an effect of disturbed expression of the cytokine and integrin system by the presence of a hydrosalpinx, thus impairing the implantation potential.

Laparoscopic salpingectomy before IVF-ET has been shown to restore IVF-ET outcomes in patients with hydrosalpinges (6-10). However, this procedure is associated with an increased risk for complications in patients with severe pelvic adhesions. Proximal occlusion of a hydrosalpinx by hysteroscopic placement of an Essure device may offer an alternative to laparoscopic surgery in these patients. Therefore, we conducted a prospective, single-arm, clinical study aiming to investigate the success rates of proximal tubal occlusion with Essure devices in subfertile women presenting with hydrosalpinges in which laparoscopy was felt to be contraindicated, as well as to observe the results of subsequent treatment with IVF-ET or frozen embryo transfers with follow-up including pregnancy and delivery.

Materials and methods

Ten patients with uni- or bilateral hydrosalpinx undergoing IVF-ET or frozen embryo transfers were included in this clinical study. A hydrosalpinx was defined as a distally occluded fallopian tube that was pathologically dilated or became pathologically dilated when patency was tested by hysterosalpingography (HSG). We included patients in this study after confirming the presence of hydrosalpinges with transvaginal ultrasound (midcyclic) and when laparoscopic surgery was

considered to be contraindicated because of extensive pelvic adhesions. Patients were excluded if their age was over 40 years and if they were not suitable for IVF treatment. Approval of the institutional review board was obtained.

The Essure device was approved by the U.S. Food and Drug Administration in 2002, and indicated for hysteroscopic tubal sterilization. Essure (Conceptus Inc., San Carlos, CA) is an expanding spring device (diameter: 2 mm; length: 40 mm) made of Nitinol and stainless steel, which contains Dacron fibres that induce a local inflammatory response and subsequent fibrosis of the proximal part of the tube. Nitinol consists of nearly equal atomic nickel–titanium (NiTi) alloy. The presence of nickel is a cause of concern related to embryologic development, but the NiTi alloy showed no cytotoxic, allergic, or genotoxic activity in animal studies, and was similar to the clinical reference material, 316 stainless steel (11). The hysteroscopic placement of the Essure devices was done under antibiotic prophylaxis (Doxycycline: 200 mg, 5 days) in the second week of the patient's menstrual cycle. The Essure devices were placed with up to four coils visible in the uterine cavity under direct hysteroscopic view using a special delivery system. Three months postprocedure an HSG was performed to evaluate proximal tubal occlusion. Thereafter, all patients underwent IVF-ET and/or frozen embryo transfer. Patients with severe endometriosis were pretreated with long-term (≤ 3 months) GnRH-agonists before IVF-ET according to Sallam et al. (12).

Results

Ten women (mean age: 33.5 years; range: 28–38 years) with unilateral (N=7) or bilateral hydrosalpinges (N=3), because of undergoing IVF, were included (Table 1). Laparoscopy was felt to be contraindicated because of previous extensive pelvic surgery because of endometriosis (N=7) and Crohn's disease (N=1) or frozen pelvis as a result of pelvic inflammatory disease (N=2). Before the placement of the Essure devices six patients underwent unsuccessful IVF treatment.

All Essure procedures were performed in an office setting. No anaesthetics were administered, except for two cases where a paracervical block was needed. Successful placement was achieved in all patients. A mean number of three coils (range: 1–4 coils) of the device spring were left protruding into the uterine cavity. No intraoperative or postoperative complications occurred. The procedure times ranged between 5 and 8 minutes. An HSG was performed after 3 months, demonstrating tubal occlusion in 9 patients.

IVF was started after a mean duration of 4.5 months following the Essure procedure (Table 2). The first two patients (cases A and B) became pregnant on their

Table 1

Demographics and Essure data.

Case	Age (years)	Duration subfertility (years)	IVF-ET prior to Essure	Pathology	Hydrosalpinx (uni/bilateral)	Essure coils in uterine cavity (N)	Tubal patency postprocedure ^a
A	32	2	Yes	Endometriosis	Unilateral	1	No
B	30	5	Yes	Endometriosis	Bilateral	3 + 3	No
C	32	3	Yes	Endometriosis	Unilateral	4	No
D	38	9	Yes	Endometriosis	Bilateral	2 + 3	Yes (Left side)
E	34	8	No	Endometriosis	Bilateral	4 + 4	No
F	36	3	No	Endometriosis	Unilateral	3	No
G	28	4	No	Endometriosis	Unilateral	3	No
H	30	2	Yes	Frozen pelvis (post-PID)	Unilateral	4	No
I	37	4	Yes	Morbus Crohn	Bilateral	4 + 3	No
J	38	3	No	Frozen pelvis (post-PID)	Unilateral	2	No

Note: PID = pelvic inflammatory disease; IVF-ET = in vitro fertilization-embryo transfer.

^aDetermined with hysterosalpingography 3 months after Essure placement.

first IVF treatment cycle. The course of these pregnancies was normal, and both patients had a spontaneous term vaginal delivery of healthy infants. Postpartum hysteroscopy showed in both cases complete tissue encapsulation of the Essure devices (Fig. 1).

In case C, the patient experienced a miscarriage nearly 7 weeks after oocyte retrieval in her first IVF cycle. Frozen embryo transfer is now pending for this patient.

Case D involved a patient in which two Essure devices were placed bilaterally. One of them (the left side) showed tubal patency at the HSG (Fig. 2). A repeat HSG has not been performed and she became pregnant after a frozen embryo transfer performed 5 months postprocedure. (The patency rate in earlier studies with HSG 3 months after hysteroscopic sterilization with Essure was 3-4%, and in all cases a repeat HSG after 6-7 months showed bilateral occlusion) (13).

Figure 1

Hysteroscopic view 3 months after vaginal delivery (patient B): complete tissue encapsulation of the Essure device. The arrow is pointing at the tissue overgrowth at the ostium tubae.



Unfortunately, she delivered at 24 weeks of gestation and her child died shortly after birth. Two weeks earlier she was admitted to an obstetric ward with complaints of discomfort in the lower abdomen and back in combination with sonographic observations of shortening cervical length. During the admission she developed a chorioamnionitis with subsequent rupture of membranes, which made the placement of an emergency cerclage impossible. Hysteroscopic evaluation after the delivery demonstrated in this case total tissue encapsulation of the left sided Essure device. On the right side only the tip of the device was visible. Six months after the delivery a frozen embryo transfer was performed, which was unsuccessful. A second frozen embryo transfer resulted in a ongoing pregnancy.

One patient, case E, did not achieve pregnancy after three IVF cycles and one frozen embryo transfer despite goodquality embryos. Two patients (cases F and G) ceased their IVF treatment after their first cycle because of partner separation. The last three patients (cases H, I, and J) from our study underwent all one unsuccessful IVF treatment cycle. One of them is currently undecided as whether to proceed with further treatment.

Discussion

In line with the pathophysiologic concepts of hydrosalpinges, any surgical intervention interrupting the communication between hydrosalpinx and uterine cavity would stop the leakage of hydrosalpinx fluid and would improve the endometrial environment for implantation. Laparoscopic salpingectomy before IVF in patients with hydrosalpinges restores IVF-ET outcomes but carries also all the risks (visceral injury, vascular damage, and unintended laparotomy) associated with laparoscopic intervention and general anesthesia (14). Our study shows that a hysteroscopic approach to proximal occlusion of hydrosalpinges with Essure devices is safe, highly effective, and feasible in an ambulatory setting. In the 10 patients that were treated no intraoperative or postoperative complications occurred. Successful placement was achieved in all patients using local anaesthetics only in 20% of the cases. The Essure devices induced complete proximal occlusion in 9 out of 10 patients.

Only in one patient (case D) was one-sided patency observed during HSG. On the other hand, hysteroscopy after her immature delivery showed total tissue encapsulation of this device, suggesting that the induced fibrosis by the Dacron fibres may take >3 months to establish complete occlusion of the proximal tubal lumen.

In the last 3 years four reports (15-18) on the use of Essure devices for the treatment of hydrosalpinx before IVF have been published. As far as we know, our study is the largest case-series on this topic. A similar study, but slightly smaller with respect to the number of patients (N=7), was presented at the annual meeting

Figure 2

Hysterosalpingogram 3 months after Essure placement (patient D).

Two devices are visible with contrast medium in the left hydrosalpinx.



Table 2

Artificial reproductive treatments and their subsequent outcomes after hysteroscopic placement of Essure devices.

Case	ART 1	Outcome	ART 2	Outcome	ART 3	Outcome	ART 4	Outcome
A	IVF	Life birth	—	—	—	—	—	—
B	IVF	Life birth	—	—	—	—	—	—
C	IVF	Miscarriage	Frozen ET	No pregnancy	—	—	—	—
D	Frozen ET	Immature delivery	Frozen ET	No pregnancy	Frozen ET	Ongoing pregnancy	—	—
E	IVF	No pregnancy	IVF	No pregnancy	IVF	No pregnancy	Frozen ET	No pregnancy
F	IVF	No pregnancy	—	—	—	—	—	—
G	IVF	No pregnancy	—	—	—	—	—	—
H	IVF	No pregnancy	—	—	—	—	—	—
I	IVF	No pregnancy	—	—	—	—	—	—
J	IVF	No pregnancy	—	—	—	—	—	—

Note: ART = artificial reproductive treatment; IVF = in vitro fertilization; ET = embryo transfer. 2009.

of the ASRM in 2007 (17). Both case-series show good pregnancy rates with IVF-ET following Essure placement, which are in line with those found after laparoscopic salpingectomy (10).

In our study five pregnancies occurred, including two term vaginal deliveries of healthy infants, a miscarriage, and a immature delivery. In case D, the immature delivery appears primary to be related to cervical insufficiency (although risk factors for cervical insufficiency are lacking), leading to a chorioamnionitis and subsequent rupture of the membranes. However, it remains difficult to rule out any influence of the visible Essure tip (seen on the right side at postpartum hysteroscopy) on this chain of events in this case.

A significant concern in using Essure devices for the treatment of hydrosalpinx in women wishing to conceive is the trailing of Essure coils into the uterine cavity and its possible effects on implantation as well as on pregnancy. Therefore, we decided, in line with other investigators (16-18), to limit the number of coils remaining in the cavity to three. Our experience is that this is usually feasible. The second-look hysteroscopies performed after delivery in our study confirmed earlier observations that deep placement of the Essure devices usually leads to total encapsulation of the device with exclusion from the uterine cavity, which is reassuring (19).

In conclusion, our study confirms earlier reports on the effectivity of Essure devices in inducing proximal tubal occlusion in infertile patients with ultrasound visible hydrosalpinges. Up to now, our study is the largest prospective case-series on this subject including second-look hysteroscopies after childbirth. Our data show successful placement in all cases without intraoperative or postoperative complications. A 40% ongoing pregnancy rate was achieved with 20% live births after one IVF-ET cycle and/or frozen embryo transfer (in this same time frame an overall live birth rate of 26% was achieved in women without hydrosalpinx (or Essure placement) treated at our IVF center). In our opinion, these results warrant a randomized comparison between laparoscopic salpingectomy and hysteroscopic placement of Essure devices for ultrasound visible hydrosalpinges in patients before IVF-ET.

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